

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Exempt Dangerous Drugs and Devices

Section Affected: 1714.5

Problem Addressed

The Pharmacy Act (Business and Professions Code sections 4000 et seq.) authorizes the Board of Pharmacy to establish and implement rules and regulations regarding the practice of pharmacy as may be necessary for the protection of the public.

Section 4057 as amended by Senate Bill 1308 (Chapter 655, Statutes of 1999) no longer contains a listing of dangerous drugs and devices that are exempt from the provisions of Business and Professions Code (B&P Code) section 4000 et seq. (Pharmacy Law) for specified entities. Amended section 4057 specifies that the listing of these dangerous drugs and devices is located in the Board of Pharmacy regulation.

This amendment became effective January 1, 2000.

The board seeks promulgate regulations to designate which dangerous drugs and devices may be stored outside a pharmacy by certain specified entities. Existing regulations do not provide for storage of dangerous drugs and devices outside a pharmacy.

Lastly, without the provisions of proposed section 1714.5, the affected parties would no longer have the ability to determine which, if any, drugs or devices requiring a prescription or chart order might be stored outside a pharmacy. Currently, the affected parties rely on the provisions of B&P Code section 4057 prior to its amendment to set the parameters for storage of the specified drugs. Since January 1, 2000, became effective, these provisions were assumed to exist in regulation.

Specific Purpose of the Regulation

The purpose of this proposal is to place in regulation a listing of dangerous drugs and devices that are exempt from storage in a pharmacy provided that the drugs or devices are obtained by an entity meeting specified licensure and practice criteria.

Prior to the amendment of section 4057, the only method for modification of the listings was through costly and time-consuming legislative action. The board sought to amend section 4057 to facilitate future modification of the listing as the need arises. The board's need to provide the necessary criteria for a critical aspect of the uninterrupted flow of patient care by the affected parties drives this proposal.

Factual Basis

Pursuant to Business and Professions Code section 4005 the Board of Pharmacy has authority to promulgate regulations to regulate the practice of pharmacy.

Section 4057 as amended by Senate Bill 1308 (Chapter 655, Statutes of 1999), specifies that the dangerous drugs and devices exempt from the requirements of Pharmacy Law for specified license holders are listed in the board's regulations.

The board intends to re-establish the listing of dangerous drugs and devices in regulation in order to complete the action initiated thorough legislation.

Underlying Data

None

Business Impact

This regulation would not have significant adverse economic impact on businesses.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No alternative which was considered would be either more effective than or equally as effective and less burdensome to affected private persons than the proposed regulation.

(8/14/00)